

Notice of Allowability

Application No.

09/833,328

Examiner

Malgorzata A. Walicka

Applicant(s)

LAEMMLE ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/15/05.
2. ☒ The allowed claim(s) is/are 8-21,23-26,29-31 and 106.
3. ☒ The drawings filed on 12 April 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☒ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>interview summary, attached</u> . |

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Filing the reformatted copy of the paper sequence listing on January 10, 2005 and Amendment after final rejection on March 15, 2005 is acknowledged. Claims 7 and 22 were previously canceled. Claims 27-28 and 32-35 have been cancelled by the current amendment. Claims 1, 9, 10, 12, 17, 18 and 30 have been amended. Claims 1-6, 8-21, 23-26 and 29-31 are pending and are the subject of this Office Action.

DETAILED ACTION

1. Objections

Objection to the paper copy of the sequence listing of Dec. 24, 2001 is withdrawn, because a new corrected copy has been filed.

2. Rejections

2.2. 35 USC section 112, first paragraph

Rejection of claims 1-6, 8-11, 13-21, 23-26 and 29-31 maintained in the Final Rejection of Dec. 16, 2004 is withdrawn, because the claims have been amended and Applicants' arguments are found persuasive.

3. Examiner's amendment

Please amend claim 31 as follows:

31. An isolated polypeptide according to claim 30 wherein said polypeptide is encoded by a polynucleotide sequence [set forth in], which comprises SEQ ID NO: 3.

Authorization for this examiner's amendment was given in a telephone interview with Mark Sandbaken on March 28, 2005.

4. Allowance

Claims 1-6, 8-21, 23-26 and 29-31 are allowed. The following is examiner's reason for allowance. Applicants disclose several C-terminus truncated forms of human plasma protease cleaving von Willebrand factor. All polypeptides comprise at their N-terminus SEQ ID NO: 1 and have molecular weight between 180-120 kD as determined by SDS-PAGE under reducing conditions. The invention is novel and nonobvious. Application or inhibition of the disclosed protease has clinical use in treatment of such diseases as thrombotic thrombocytopenic purpura or von Willebrand disease and acquired myeloproliferation syndrome. The closest prior art is that by Furlan et al. (Partial Purification and Characterization of a Protease from Human Plasma Cleaving von Willebrand Factor to Fragments Produced by *in Vivo* Proteolysis, Blood, 1996, 87/10, 4223-4234). Furlan et al. do not teach the polypeptide whose N-terminal comprises SEQ ID NO: 1 or SEQ ID NO: 4 or SEQ ID NO: 1 immediately followed by SEQ ID NO: 15, furthermore Furlan et al. isolated their proteins using different method than that used by the instant application. In addition, under reducing conditions, Furlan et al. did not obtain the bands with molecular weight of 180 kD, 170 kD, 160 kD and 120 kD as recited by the instant claims, but polypeptide bands of 65 and 50 kD, and only a small of total protein migrated with and M_r greater than 80. In conclusion, the

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polypeptides having proteolytic activity in Furlan's et al. paper are not that disclosed in the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


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